DOCKET NO.:ALZA-0020 **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Lam, et al.

Confirmation No.: 5468

Application No.: 09/253,317

Group Art Unit: 1614

Filing Date: February 19, 1999

Examiner: Zohreh A. Fay

For: Methods and Devices for Providing Prolonged Drug Therapy

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF SUNEEL K. GUPTA

I, Suneel K. Gupta, hereby declare that:

1. I am one of the named inventors of the above-identified patent application, and make this declaration in support thereof.

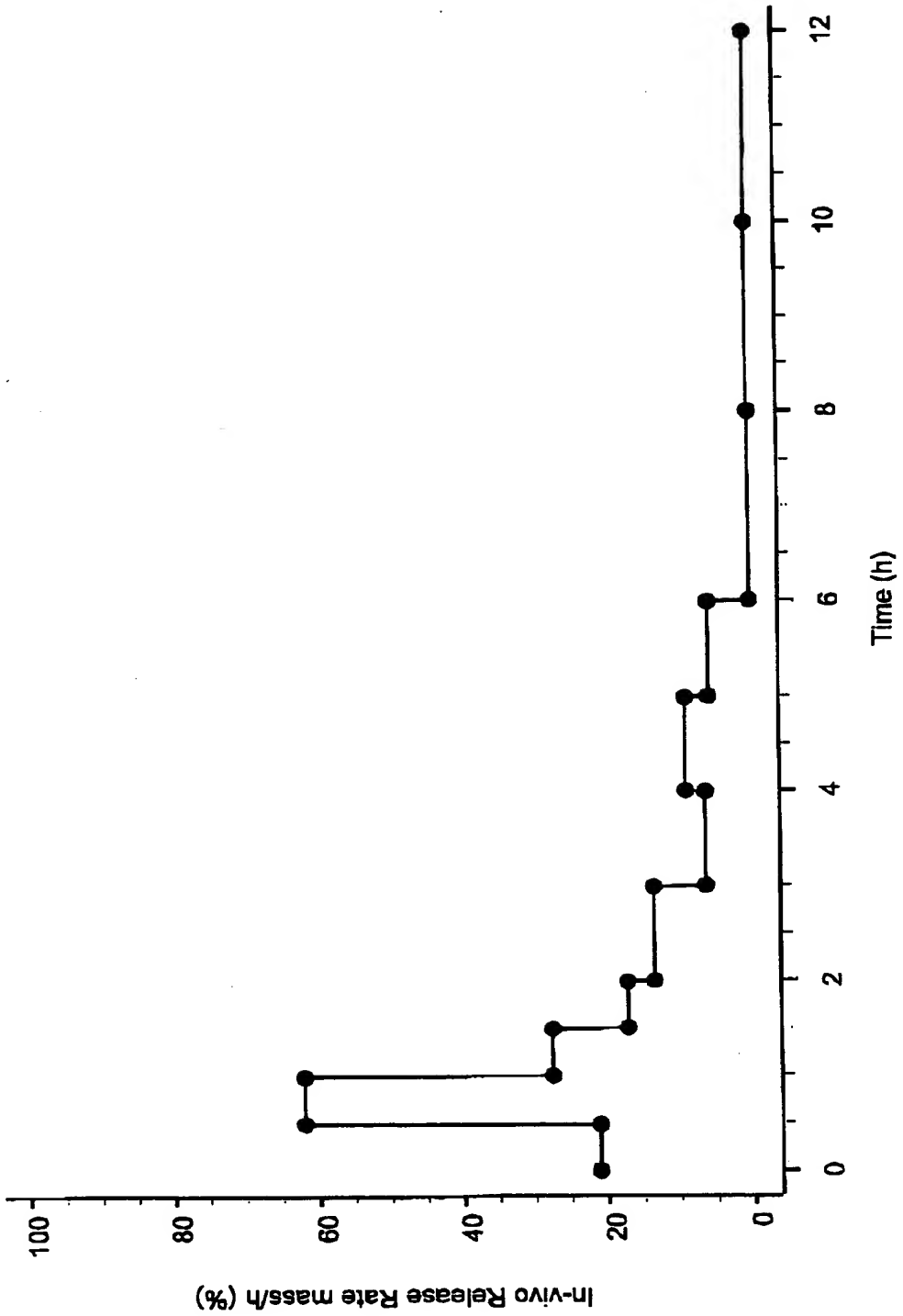
2. I have been practicing in the field of drug delivery for at least the last 16 years. I received my Ph.D. degree in Pharmacokinetics from the University of Manchester in Manchester, United Kingdom in 1987, and served a post-doctoral fellowship in Pharmacokinetics and Pharmacodynamics at the University of California, San Francisco from 1987 to 1989. I joined Alza Corporation in 1989 as a Staff Scientist in the Biopharmaceutics department, and have held various positions with Alza since then. I currently hold the position of Senior Vice President & Distinguished Research Fellow.

3. I have been asked to assess the extent to which one can determine the rate at

which the Ritalin SR product releases methylphenidate based on the plasma concentration data for that product that are provided in Patrick, *et al.*, *Biopharmaceutics & Drug Disposition* **1989**, *10*, 165 ("the Patrick reference"). To make this determination, I supervised application of the Wagner-Nelson mathematical deconvolution method (Wagner, *et al.*, *J. Pharm . Sci.* **1963** *52*, 610) to the plasma concentration that the Patrick reference discloses in Figure 2. This type of deconvolution is routinely performed by those skilled in the field of pharmaceutical sciences and drug delivery, and I have deconvoluted plasma concentration data or supervised the deconvolution of such date numerous times during the course of my career.

4. By deconvoluting the plasma concentration data that the Patrick reference discloses in Figure 2, one is able to approximate the release rate that the Ritalin SR product would have needed to achieve to produce the plasma concentrations that the reference reports. Although there exist a number of different methods that potentially could be used to deconvolute the Ritalin SR plasma concentration data that the Patrick reference provides, the Wagner-Nelson method was one of the first to appear in the literature and one that I believe to produce representative results.

5. By applying the Wagner-Nelson method to the data that the Patrick reference reports in Figure 2, I was able to determine that the methylphenidate release rate for the Ritalin SR actually decreased during most of the 12-hour period over which the authors gathered their data. This is shown in the following graph plotting the data that I obtained using the Wagner-Nelson method:


Release Rate Profiles
Following Methylphenidate Treatment
Calculated Using Wagner-Nelson Method for Ritalin-SR
In-vivo Release Rate mass/h (%)
100
80
60
40
20
0
0
2
4
6
8
10
12
Time (h)

As this graph shows, the data reported in the Patrick reference indicates that although the rate of methylphenidate release increased over approximately the first hour with the Ritalin SR product, it decreased in a fairly steady manner thereafter. I do not believe that anyone skilled in the field of drug delivery would consider this to constitute the "ascending release rate over an extended period of time" that I understand to be recited in the claims of the above-identified patent application.

6. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

July 17, 2003

Suneel K. Gupta

CURRICULUM VITAE

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A. INDUSTRIAL EXPERIENCE

1989- **Alza Corporation, Mountain View, CA 94043.** (Wholly Owned subsidiary of Johnson and Johnson, since June 2001)

2002- Sr. Vice President & Distinguished Research Fellow, Experimental Pharmacology and Clinical Research
Member of the Perspective team. The leadership team was the top 30 or so executives in JnJ evaluating the Global capture of innovation in science and technology.
Member of Drug Evaluation management team and Integrated Drug Review committees focused on the drug development from discovery to through clinical development.

2000- 2002 Vice President & Principal Scientist, Clinical Research & Pharmacology
1999- 2000 Executive Director & Principal Scientist, Clinical Pharmacology
1997 -1999 Senior Director & Senior Research Fellow, Clinical Pharmacology
1995 -1997 Director, Clinical Pharmacology
1993 -1995 Associate Director & Research Fellow, Clinical Pharmacology
1991 -1993 Manager & Research Scientist, Pharmacokinetics and Pharmacodynamics
1989 -1991 Staff Scientist, Biopharmaceutics

- NDA Filing and approval of Duragesic® (Fentanyl Transdermal System). Presentation to FDA advisory committee for Duragesic® on (1987-88).
- NDA Filing and approval of three Cough-Cold products Effidac® (Pseudoephedrine, Chlorpheniramine, and Brompheniramine and Pseudoephedrine Combo). Responsible for pharmacokinetic studies (1987-94).
- NDA Filing and approval of Nicoderm® (Nicotine Transdermal System). Responsible for pharmacokinetic studies, including PK and PD model development for transdermal products and wrote NDA-PK summary (1988-91).
- NDA Filing and approval of COVERA-HS® (Verapamil). Overall responsible for the clinical pharmacology package, including Clin Pharm studies, data analysis, reports, NDA clin pharm summary, Developed population PK/PD models based on Phase-III data (1993-95).
- NDA Filing and approval of Testoderm-TTS® (Testosterone Transdermal System). Responsible for clinical pharmacology package, which was the basis of approval (1994-96).
- NDA Filing and approval for Ditropan-XL® for urinary incontinence. Overall responsible for the clinical pharmacology package. Developed Population PK/PD models for urge Incontinence and side effects based on Phase-III study data (1994-98). Designed studies to demonstrate differences of Ditropan-XL in anti-cholinergic side effects.
- NDA for Electrotransport-Fentanyl system for acute pain relief. The first ethical electrotransport system. Responsible for Phase I and Phase II studies (1989-).
- NDA filing and approval for Concerta® for attention deficit hyperactive disorder. Invented the target delivery profile. Developed a activity monitor as a surrogate for efficacy, developed questionnaire for treatment effect. Patented the delivery profile to achieve once a day efficacy. Responsible for Phase I, II & III studies. (1994-99).

1981-1984 **Ciba-G igy Ltd., Kandla, India.** *(Manufacturing)*

- Manufacturing & packaging of Rimactane® (Refamycin) Capsules.
- Manufacturing (freeze-drying) & packaging of Cefamycine injections.
- Manufacturing and packaging of Binaca® tooth paste.

B. PRESENT RESPONSIBILITIES

- Overall research plans and regulatory approval strategies for pre-clinical, clinical pharmacology and clinical research packages of all ALZA products.
- Overall responsible for design, conduct and analysis of all Pre-clinical, Phase 1 & 2 studies for ALZA for both U.S. and international submissions.
- Participate in project planning and development teams and interact regulatory and post-marketing research.
- Participate in ALZA's legal defense teams for patent infringement and liability lawsuits.
- Participate in in-licensing and out-licensing activities.

C. HONORS AND AWARDS

- Johnson Medal for R&D 2002 (JnJ's highest scientific honor)
- ALZA Founder's award 2001 (alza's highest honor)
- ALZA Top Performer's award, 1994, 1996 & 1997.
- Frederick Craven Moore award, 1985-1987.
- First in Class with Honors in M. Pharm, 1981.
- Best Student, Class of 1978. First in Class with Honors In B Pharm 1978.

D. EDUCATION

1987-1989	**Post-Doctoral Fellow** - University of California, San Francisco, CA. Supervisor: *Prof. Leslie Z. Benet.*
1985-1987	**Ph.D.** - University of Manchester, Manchester, United Kingdom. Supervisor: *Prof. Malcolm Rowland.*
1982-1984	**I.C.W.A.** - Institute of Cost & Works Accountants of India, Calcutta, India.
1979-1981	**M. Pharm.** - Banaras Hindu University, Varanasi, India.

E. CONTINUING EDUCATION

- *Executive Program in Strategy and Organization.* Graduate Business School, Stanford University. August 2002.
- *Finance and Accounting for Non-Financial Executive Program.* Graduate Business School, Stanford University. May 2002.
- PERI course in "Drug Development", May 1996

F. PATENTS

- US 6512010 01/28/2003 Formulations for the administration of fluoxetine
- US 6219576 04/17/2001 Programmed adjustment of electric current to provide desired electrically assisted transdermal drug delivery rate
- EP01083879A1 03/21/2001 Methods and devices for providing prolonged drug therapy

- EP01047475A1 11/02/2000 Iontophoresis with programmed adjustment of electric current
- US 6136327 10/24/2000 Stereo specific delivery of a drug using electrotransport
- EP01035891A1 09/20/2000 Stereospecific delivery of a drug using electrotransport
- US 6034101 03/07/2000 Dosage form and method for administering drug
- WO09962496A1 12/09/1999 Methods and devices for providing prolonged drug therapy
- US 5983130 11/09/1999 Electro transport agent delivery method and apparatus
- EP00946184A2 10/06/1999 Novel formulations for the administration of fluoxetine
- WO09948494A1 09/30/1999 Sustained-release composition of oxybutynin with reduced xerostomia effect
- EP00932388A2 08/04/1999 Dosage Form and method for administering drug
- WO09930775A1 06/24/1999 Iontophoresis with programmed adjustment of electric current
- WO09927990A2 06/10/1999 Stereo specific delivery of a drug using electro transport
- EP00836513A1 04/22/1998 Electro transport agent delivery method and apparatus
- WO09814168A2 04/09/1998 Dosage form and method for administering drug
- WO09802169A2 01/22/1998 Novel formulations for the administration of fluoxetine
- WO09640365A1 12/19/1996 Electro transport agent delivery method and apparatus

G. PUBLICATION SUMMARY

• Plenary Seminars	18
• Book Chapters:	6
• Papers:	72
• Abstracts:	79
• Total Publications:	174

PUBLICATIONS

PLENARY LECTURES AT WORKSHOPS & SYMPOSIA

- American Association of Pharmaceutical Scientists, Feb 1993, New Jersey "Effect of stereo specific assay on pharmacokinetic and Pharmacodynamic Modeling".

- IBC Conference, Feb. 1996, Washington DC "Role of PK/PD modeling and development of controlled release products".

- VIth World Conference on Clinical Pharmacology and Therapeutics, Aug 1996, Buenos Aires, Argentina "The relevance of the PK/PD interface in the development of controlled release systems".

- Active drug metabolites and stereoisomers: opportunities in drug development Jan 1997. Washington DC " Site-specific presystemic metabolism of oxybutynin following oral administration".

- American Association of Pharmaceutical Scientists, April 1997, San Francisco, CA. "The role of pharmacokinetics and Pharmacodynamics in the design of controlled release systems"

- 5th European Society of Anesthesiologist, May 1997, Laussane, Switzerland "Mechanism of transdermal drug delivery".

- American College of Clinical Pharmacology, Sept 97, Phoenix, AZ. "Electrically Assisted Transdermal Drug Delivery ".

- American Academy of Child & Adolescent Psychiatry, Oct 97, Toronto, Canada. "Phase I Trial in the laboratory classroom: Development of concept".

- 3rd International symposium on measurement and kinetics of in vivo drug effects, May 98, Noordwijkerhout, The Netherlands. "Dose-response modeling of efficacy (urge urinary incontinence) and side effects (dry mouth) of oxybutynin"

- 9th Japanese- American Conference on Pharmacokinetics and biopharmaceutics, July 98, Nagoya Japan. "Role of PK/PD in designing controlled release products"

- Establishing bioequivalence. IIR Conference, Philadelphia, June. 1999, "Determining bioequivalence of a controlled release product"

- Chaired the Conference "Clinical Trials for drug delivery systems". San Francisco, July. 1999. And Presented "Designing a clinical study to test formulation concepts

- Chaired the Conference "Clinical Pharmacokinetics and Pharmacodynamics". Arlington VA. Feb 2000, and presented "Estimating and comparing the therapeutic index by applying population PK/PD models to controlled release products.

- AAPS/FDA workshop Biopharmaceutics in the new millennium: Regulatory approaches to bioavailability and bioequivalence. IR to CR Bridging studies: Industry perspective. Washington DC, Sept 2000.

- FDA/DIA workshop Application of Pharmacokinetics/Safety information in drug development and regulatory decisions. Implication of PK/Safety information on formulation selection in drug development. Washington DC, April 2001.

- EUFFS World Conference on drug absorption and drug delivery. From Immediate to extended release products: Delivering the goods through PK/PD modeling. Copenhagen June 2001.

- ISPE Annual meeting. Advances in Drug Delivery- The role of pharmacological discovery in drug delivery. Las Vegas, October 2001.

- FDA symposium on oral modified release of solid oral dosage forms. Washington, September 2002.

PAPERS PUBLISHED

1. **Gupta, S. K.** and Gupta, R. K. Pharmacy of radiopharmaceuticals. Pharm Student 20:39-44; 1980.

2. **Gupta, S. K.**, Pandit, J. K. and Gode K. D. Effect of crystal form on the oral absorption of Phenylbutazone (II). Int. J. Pharmaceutics 21:29-132; 1984.

3. Rowland, M. and **Gupta, S. K.** Cyclosporin-phenytoin interaction: Re-evaluation using metabolite data. Br. J. Clin. Pharmacol. 24:329-334; 1987.

4. **Gupta, S. K.**, Solomon, L. R., Johnson, R. W. G. and Rowland, M. Pharmacokinetics of cyclosporin-A: Influence of intravenous dosing rate in renal transplant patients. Br. J. Clin. Pharmacol. 24:519-526; 1987.

5. Legg, B., **Gupta, S. K.** and Rowland, M. A model to account for the variation in cyclosporin binding to plasma lipids in transplant patients. Thera. Drug Monitor. 10:20-27; 1988.

6. **Gupta, S. K.**, Bakran, A., Johnson, R. W. G. and Rowland, M. Erythromycin enhances absorption of cyclosporin-A. Br. J. Clin. Pharmacol. 25:401-402; 1988.

7. Legg, B., **Gupta, S. K.**, Rowland, M., Johnson, R. W. G. and Solomon. L. R. Cyclosporin: Pharmacokinetics and detailed studies of plasma and erythrocyte binding during intravenous and oral administration. Eur. J. Clin. Pharmacol. 34:451-460; 1988.

8. **Gupta, S. K.**, Bakran, A., Johnson, R. W. G. and Rowland, M. Pharmacokinetics of cyclosporin: Influence of rate-duration profile of an intravenous infusion in renal transplant patients. Br. J. Clin. Pharmacol. 27:353-357; 1989.

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10. **Gupta, S. K.**, Bakran, A., Johnson, R. W. G. and Rowland, M. Cyclosporin-erythromycin interaction in renal transplant patients. Br. J. Clin. Pharmacol. 27:475-481; 1989.

11. **Gupta, S. K.** and Benet, L. Z. HPLC measurement of cyclosporine and its metabolites in blood, plasma and urine. J. Liq. Chromatogr. 12:451-1462; 1989.

12. **Gupta, S. K.** and Benet, L. Z. Absorption kinetics of cyclosporine in healthy volunteers. Biopharm. and Drug Dispos. 10:591-596; 1989

13. **Gupta, S. K.** and Benet, L. Z. High fat meals increase the clearance of cyclosporine. Pharm. Res. 7:46-48; 1990.

14. **Gupta, S. K.**, Manfro, R., Tomlanovich, S., Gambertoglio, J., Garovoy, M. and Benet, L. Z. Pharmacokinetics of cyclosporine in healthy volunteers following oral and intravenous administration and effect of food on absorption of cyclosporine. J. Clin. Pharmacol. 30:643-653; 1990.

15. **Gupta, S. K.**, Southam M., Gale, R., and Hwang, S. S. System functionality and physio-chemical model of fentanyl transdermal system. J. Pain Symptom Manage. 7:17-26; 1992.

16. **Gupta, S. K.**, Southam, M. and Hwang, S. S. Pharmacokinetics of droperidol in healthy volunteers following intravenous infusion and rectal administrations from an osmotic drug delivery module. Pharm. Res. 9:694-696; 1992.

17. **Gupta, S. K.**, Okerholm, R. A., Coen, P., Prather, R.D, and Gorsline J. Single and multiple dose pharmacokinetics of Nicoderm® (nicotine transdermal system). J. Clin. Pharmacol. 33:69-174; 1993.

18. Portenoy, R. K., Southam, M. A., **Gupta, S. K.**, Lapin, J., Layman, M., Inturissi, C. E. and Foley, K. Transdermal fentanyl for cancer pain: Repeated dose pharmacokinetics. Anesthesiology 78:36-43; 1993.

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20. Haak, R. and **Gupta, S. K.** Pulsatile drug delivery from electro-transport therapeutic systems. J. Control. Rel. 95-108; 1993.

21. **Gupta, S. K.**, Hwang, S.S., Benet, L.Z. and Gumbleton, M. Interpretation and utilization of effect and concentration data collected in an *in-vivo* pharmacokinetic and *in-vitro* pharmacodynamic study. Pharm. Res. 10:889--894; 1993.

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28. **Gupta, S. K.,** Okerholm, R. A., Eller, M., Wei, G., Rolf, C. N. and Gorsline, J. Comparison of pharmacokinetics of two transdermal nicotine systems: Nicoderm® and Habitrol. J. Clin. Pharmacol. 35: 493-498; 1995.

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33. **Gupta, S. K.,** Atkinson, L. A., Tu, T. and Longstreth, J. Age and gender related changes in stereoselective pharmacokinetics and pharmacodynamics of verapamil and norverapamil. Br. J. Clin. Pharmacol. 40: 325-331; 1995

34. **Gupta, S. K.,** Atkinson, L. A., Yih, B. M. and Longstreth, J. Effect of posture, time of administration, and food on pharmacokinetics and pharmacodynamics of verapamil. J. Clin. Pharmacol. 35: 1083-1093; 1995.

35. **Gupta, S. K.,** Atkinson, L. A., Yih, B. M. and Longstreth, J. Simultaneous first-order and capacity-limited elimination kinetics following oral dosing of verapamil. J. Clin. Pharamacol. J. Clin. Pharmacol. 36: 25-34; 1996.

36. Hale, M., Gillespie, W.R., **Gupta, S.K.,** Tuk, B. and Holford, N. Clinical trial simulation: Streamlining your drug development process. Applied Clinical Trials. 5: 35-40; (1996).

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38. **Gupta, S,K.**, Shah, J., Guinta, D and Hwang, S. Multiple dose pharmacokinetics and pharmacodynamics of OROS and immediate release amitryptyline hydrochloride formulations. J. Clin. Pharmacol. 38: 60-67; (1998).

39. Yu, Z ., **Gupta, S.K.**, Hwang, S.S., Kipnes, M.S., Mooradian, A.D., Snyder, P. and Atkinson, L. Testosterone Pharmacokinetics of an Investigational Transdermal System in Hypogonadal Men. J. Clin. Pharmacol. 37: 1129-1138; (1997).

40. Yu, Z ., **Gupta, S.K.**, Hwang, S.S., Cook, D.M., Duckett, M.J., and Atkinson. L. Transdermal Testosterone Administration in Hypogonadal Men: Comparison of Pharmacokinetics at Different Sites of Application and at the First and Fifth Days of Application. J. Clin. Pharmacol. 37: 1139-1145; (1997).

41. **Gupta, S,K.**, Shah, J., Guinta, D and Hwang, S. Multiple dose pharmacokinetics and pharmacodynamics of OROS and immediate release amitryptyline hydrochloride formulations. J. Clin. Pharmacol. 38: 60-67; (1998).

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43. Park, K., Verotta, D., **Gupta, S. K.** and Sheiner, L. B. Passive vs electrotransport-facilitated transdermal absorption of ketorolac. Clin. Pharm. Ther. 63: 303-315; (1998).

44. **Gupta, S. K.**, Southam, M. and Klausner, M. Effect of current density on pharmacokinetics following continuous or intermittent input from a fentanyl Electrotransport system. J. Pharm. Sci. 87: 976-981; (1998).

45. **Gupta, S. K.**, Bernstein, K., Noorduin, H., Van peer, A., Sathyan, G., and Haak, R. Fentanyl delivery from an electrotransport system: Delivery is a function of total current, not duration of current. J. Clin. Pharm. 38: 951-958; (1998).

46. Park, K., Verotta, D., **Gupta S. K.**, and Sheiner, L.B. Use of pharmacokinetic/pharmacodynamic model to design an optimal dose input profile. J. Pharmacokin. and Biopharm. 26: 471-492; (1998).

47. **Gupta S. K.**, and Sathyan, G. Pharmacokinetics of an oral once a day controlled release oxybutynin formulation compared with immediate release oxybutynin. J. Clin. Pharmacol. 39: 289-296; (1999).

48. Collins, J.J., Dunkel, I. J., **Gupta, S. K.**, Inturrisi, C. E., Lapin, J., Palmer, L. N., Weinstein, S. M. and Portenoy, R. K. Transdermal fentanyl in children with cancer pain: feasibility, tolerability, and pharmacokinetic correlates. J. Pediatrics. 134: 319-323; (1999)

49. Shah, J., Langmuir, V. and **Gupta, S. K.** Feasibility and functionality of OROS Melatonin in healthy subjects. J. Clin. Pharmacol. 39: 606- 612; (1999).

50. **Gupta, S. K.**, Sathyan, G., Lindemulder, E., Ho, P., Sheiner, L. and Aarons, L. Quantitative characterization of therapeutic index: Application of mixed-effects

modeling to evaluate oxybutynin dose-efficacy and dose-side effect relationship. Clin. Pharmacol. Theu. 65: 672- 684; (1999).

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53. **Gupta, S. K.** and Sathyan, G. Reproducible fentanyl doses delivered intermittently at different intervals from an electrotransport system. J. Pharm. Sci. 88: 835-841; (1999).

54. Swanson, J. M., **Gupta, S. K.**, Guinta, D., Flynn, D., Agler, D., Lerner, M., Williams, L., Shoulson, I. And Wigal, S. Acute tolerance to methylphenidate in the treatment of attention deficit hyperactivity disorder in children. Clin. Pharmacol. Theu. 66: 295-305; (1999).

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57. **Gupta, S. K.**, Lindemulder. B. and Sathyan, G. Modeling of circadian testosterone in healthy volunteers in healthy men and hypogonadal men. J. Clin. Pharmacol. 40; 731- 738 (2000).

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62. Sathyan, G., Hu, W. H. and **Gupta, S.K.** Lack of effect of food on the pharmacokinetics of an extended-release oxybutynin formulation. J. Clin. Pharmacol. 41: 187-192 (2001).

63. Pitsiu, M., Sathyan, G., **Gupta, S. K.** and Verotta, D. A semi parametric deconvolution model to establish in-vivo-in-vitro correlation applied to OROS Oxybutynin. J. Pharm. Sci. 90: 702-712 (2001).

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